K070966

510(K) SUMMARY

JUL 20 2007

1. Applicant/Sponsor: Gold Standard Orthopaedics, LLC.
1226 Rowan St.
Louisville, KY 40203

2. Contact Person: David Baughman, President
David06@Baughmangroup.com
Phone (502) 581-8770

3. Proprietary Name: GSO GS1 Spinal System

4. Common Name: Spinal Implants

5. Classification Names: Pedicle screw spinal system, 21 CFR 888.3070
Spinal interlaminal fixation orthosis, 21 CFR 888.3050

Product Codes: MNI, KWP, MNH

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   - CD Horizon Spinal System – Medtronic Sofamor Danek, Inc. (K031833)
   - Synergy Spinal System – Interpore Cross International (K010515)

7. Device Description:

The GSO GS1 Spinal System consists of rods, screws, hooks, and adjustable crosslink that can be locked rigidly into various configurations to build a spinal construct specific to the needs of each individual patient. The implants are attached to the spine posteriorly by means of screws and/or hooks joined with rods. Crosslink components are used to attach two rods in parallel. The GSO GS1 Spinal System can be installed with any suitable instrumentation.

The GSO GS1 Spinal System components are manufactured from CP Titanium conforming to ASTM F67 and Ti-6Al-4V Titanium alloy conforming to ASTM F136. Devices are available in various diameters, lengths and sizes.

8. Intended Use:

The GSO GS1 Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. It is intended to be used as a temporary construct that assists normal healing and is not intended to replace normal body structures. The GSO GS1 Spinal System should be removed after fusion.

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As a pedicle screw system, the GSO GS1 Spinal System is intended for patients: (a) having severe spondylolisthesis (Grade 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); (c) who are receiving fusions using autogenous bone graft only; and (d) who are having the device removed after the development of a solid fusion mass.

In addition, when used as a pedicle screw system, the GSO GS1 Spinal System is indicated for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a posterior, non-cervical, non-pedicle screw and/or hook fixation system, the GSO GS1 Spinal System is indicated for:

1. Degenerative disc disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Idiopathic scoliosis
3. Kyphotic deformities of the spine
4. Paralytic scoliosis and/or pelvis obliquity
5. Vertebral fracture or dislocation
6. Neuromuscular scoliosis associated with pelvic obliquity
7. Vertebral fracture or dislocation
8. Tumors
9. Spondylolisthesis
10. Stenosis
11. Pseudarthrosis
12. Unsuccessful previous attempts at spinal fusion

For posterior, non-pedicle, screw use, the GSO GS1 screws are intended for sacral/iliac attachment only and the GSO GS1 hooks and crosslinks are intended for thoracic and/or lumbar use only.

In all cases, instrumentation must be at least 1 cm from any major vessel.

9. Summary of Technologies/Substantial Equivalence:

The GSO GS1 Spinal System has a similar design and is manufactured from the same materials as the CD Horizon Spinal System – Medtronic Sofamor Danek, Inc. (K031833) and the Synergy Spinal System – Interpore Cross International (K010515). When used as a pedicle screw system, the GSO GS1 Spinal System has the same indications as both of the predicate devices. When used as a posterior, non-

cervical, non-pedicle screw and/or hook fixation system the GSO GS1 Spinal System has the same indications as the Synergy Spinal System.

10. Non-Clinical Testing:

Mechanical testing conducted according to ASTM F1717 demonstrates that the failure loads for the GSO GS1 Spinal System are greater than published failure loads for the Synergy Spinal System.

11. Clinical Testing:

Clinical testing was not necessary to demonstrate the substantial equivalence of the GSO GS1 Spinal System to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2007

Gold Standards Orthopaedics, LLC
% Mr. David Baughman
President
1226 Rowan St.
Louisville, Kentucky 40203

Re: K070966
Trade/Device Name: GS0 GS1 Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI, MNH
Dated: June 11, 2007
Received: June 13, 2007

Dear Mr. Baughman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bone MD

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070966

Device Name: GSO GS1 Spinal System

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070966

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Concurrence of CDRH, Office of Device Evaluation (ODE)